Complete Summary

GUIDELINE TITLE

Osteoporosis and bone mineral density.

BIBLIOGRAPHIC SOURCE(S)

Richmond BJ, Dalinka MK, Daffner RH, Bennett DL, JA Jacobson, Resnik CS, Roberts CC, Rubin DA, Schweitzer ME, Seeger LL, Taljanovik M, Weissman BN, Haralson RH, Expert Panel on Musculoskeletal Imaging. Osteoporosis and bone mineral density. [online publication]. Reston (VA): American College of Radiology (ACR); 2007. 12 p. [62 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: American College of Radiology (ACR), Expert Panel on Musculoskeletal Imaging. Osteoporosis and bone mineral density. Reston (VA): American College of Radiology (ACR); 2001. 17 p. (ACR appropriateness criteria). [49 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Osteoporosis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of bone mineral density (BMD) measurement procedures for osteoporosis

TARGET POPULATION

Patients at risk of developing osteoporosis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Dual X-ray absorptiometry (DXA)
    - Posteroanterior (PA) spine
    - Proximal femur
    - Femoral neck
    - Total hip
    - Forearm
    - Lateral spine
    - Total body calcium
    - Vertebral fracture assessment (VFA)
2. Quantitative computed tomography (QCT)
    - Spine
    - Proximal femur
3. Peripheral quantitative computed tomography (pQCT)
4. Single x-ray absorptiometry/dual energy x-ray absorptiometry (SXA/DXA)
    - Heel
    - Wrist
5. Quantitative ultrasound (QUS)
    - Heel

6. X-ray
    - Thoracic and lumbar spine
7. Radiographic absorptiometry
8. Height by stadiometer

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Osteoporosis and Bone Mineral Density

Variant 1: Identification of low bone density and fracture risk. Females, postmenopausal, greater than 50 years old. Males greater than 50 years old with risk factors. All races.

Radiologic Procedure	Rating	Comments	RRL*
DXA PA spine	9		Min
DXA proximal femur and femoral neck and total hip	9		Min
QCT spine	8	Preferred method of evaluation if DXA not available or cannot be performed.	Min
QUS heel	4	Can be used for preliminary evaluation of patients at risk for fracture. If abnormal, DXA may follow.	None
DXA forearm	3	Only if hip/spine or hip/hip can't be done or patient over the table limit for weight. Primary site for patients with hyperparathyroidism.	Min
SXA/DXA heel	3		Min
QCT proximal femur	3	Limited clinical experience. Currently, primarily a research tool.	Min
pQCT	2		Min
X-ray thoracic or lumbar spine	2	Useful for diagnosing stress fractures, not osteoporosis.	Low
Radiographic absorptiometry	1		Min
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- World Health Organization (WHO) diagnostic criteria was originally made for 65-year-old postmenopausal women using DXA of the spine, femoral neck, and forearm, T-score.
- ISCD position statements changed indications to 50-year-old males and postmenopausal females using the WHO diagnostic criteria. T-score and Z-

score are used to further evaluate non-caucasian individuals with an age-matched reference data base.

- Forearm scans are used for hyperparathyroidism primary site, obesity (over table limit), and as a second site if only one other is available. Preference is for two sites beginning with hip/AP spine; if spine cannot be scanned then use hip/hip; if only one hip is available then use hip/forearm or alternatively hip/total body. Total body is rarely used in adults, especially for follow-up unless total body composition is measured.
- Fracture risk assessment is part of reporting BMD and should be a combination of clinical risk factors and BMD. Relative fracture risk should be defined as to what group the patient is being compared to – young adult or age matched.
- Any device above can predict fracture risk, but if the patient has had a DXA or QCT, the fracture risk should be based on that study. Once DXA or QCT is begun, a peripheral device should not be used. Conversely, if a patient is at risk with a peripheral device then DXA (preferably for diagnosis) or QCT should be performed and followed on that specific device. Once treatment has started then fracture risk is more difficult to estimate.

Variant 2: Follow-up. Patients demonstrated to have risk for fracture or low density.

Radiologic Procedure	Rating	Comments	RRL*
DXA PA spine	9		Min
DXA proximal femur and femoral neck and total hip	9		Min
QCT spine	8		Min
DXA forearm	3	Response to treatment significantly slower. Primary site for patients with hyperparathyroidism.	Min
QCT proximal femur	3		Min
DXA lateral spine	1	Low precision and inadequate reference database	Min
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- Follow-up scans are after the diagnostic scan. BMD is compared in gm/cm^2 – NOT T-score or Z-score.
- QCT reported in g/cm^3.

- Follow-up scans are used to determine bone loss or gain in patients at risk for loss and not taking treatment to help make a decision about treatment, or in patients undergoing treatment to determine compliance, efficacy.
- An example of a patient who should have follow-up is one being treated with steroids.
- The patient is followed every 2 years (postmenopausal women) until BMD stabilizes. Then follow-up can be lengthened unless risk factors or treatment changes.

Variant 3: Identify low BMD. Premenopausal females with risk factors. Males 20 to 50 years old with risk factors. All races.

Radiologic Procedure	Rating	Comments	RRL*
DXA PA spine	9		Min
DXA proximal femur and femoral neck and total hip	9		Min
QCT spine	8		Min
QCT proximal femur	3		Min
SXA/DXA heel	3		Min
DXA forearm	2	Only if hip/spine or hip/hip cannot be done or patient over the table limit for weight. Primary site for patients with hyperparathyroidism.	Min
QUS heel	2		None
pQCT	2	Limited usage in United States.	Min
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- WHO diagnostic criteria does not apply to this group, Z-score ONLY is used (2 standard deviation or more below age matched reference database) to determine whether BMD is below expected for age.
- There are no fracture risk data for BMD in this age group.
- Peripheral devices above determine fracture risk and suggest low BMD.

Variant 4: Follow-up to low BMD. Premenopausal females with risk factors. Males 20 to 50 years old with risk factors. All races.

Radiologic Procedure	Rating	Comments	RRL*
DXA PA spine	9		Min
DXA proximal femur and femoral neck and total hip	9		Min
QCT spine	8		Min
QCT proximal femur	3		Min
DXA lateral spine	2	Precision less than for PA spine. Technically demanding.	Min
DXA forearm	1	Primary site for patients with hyperparathyroidism.	Min
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- BMD in gm/cm^2, NOT Z-score, is used for follow-up comparison.
- QCT reported in g/cm^3.

Variant 5: Diagnosis. Males and females greater than 50 years old with advanced degenerative changes of the spine +/- scoliosis.

Radiologic Procedure	Rating	Comments	RRL*
DXA proximal femur and femoral neck and total hip	9	When PA spine cannot be assessed, hip/hip (bilateral) scans should be performed. If only one hip is available for assessment, hip and forearm can be used.	Min
QCT spine	8		Min
DXA forearm	3	Appropriate site for patients with hyperparathyroidism.	Min
QTC proximal femur	3		Min
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- Spine cannot be used with more than 2 compression fractures. A minimum of 2 vertebral bodies is required for adequate assessment of BMD.
- Follow-up and fracture risk assessment are the same as they are for previous variants for 50 year olds.

Variant 6: Identify low BMD. Pediatric patients (less than 20 years old) with risk factors.

Radiologic Procedure	Rating	Comments	RRL*
DXA total body calcium	9		Min
DXA PA spine	6	Incomplete database information. More useful in teens after fusion of epiphyses.	Min
QCT spine	6	Should be performed in experienced setting. Higher radiation dose than DXA.	Min
DXA total hip	3	Not useful before skeletal maturity.	Min
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- WHO diagnostic criteria does not apply. Z-score only is used (2 standard deviations or lower than age-matched reference database) is to determine if BMD lower than expected for age.
- Limited hip DXA database.
- Reporting method for pediatric BMD is controversial at present.

Variant 7: Follow-up. Pediatric patients (less than 20 years old) with risk factors.

Radiologic Procedure	Rating	Comments	RRL*
DXA total body calcium	9	BMD Z-score is used for diagnosis on first scan. Bone mineral content can be used for follow-up.	Min
QCT spine	7		Min

Radiologic Procedure	Rating	Comments	RRL*
DXA PA spine	5	Most accurate in patients that are skeletally mature.	Min
DXA total hip	2	Most accurate in patients that are skeletally mature.	Min
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- Follow-up in pediatrics is not defined. Clinical decisions determine follow-up except for steroid treated patients who are scanned at the same interval at any age.
- Confounding factors in follow-up of these patients are a changing area because of increasing size of bone and how to determine if BMD change is real, QCT avoids this pitfall because of volumetric measurement.
- Very little data are available for hip DXA.

Variant 8: Suspected fracture, incident or prevalent, of a vertebral body based on clinical history, height loss, or patient treated with steroids.

Radiologic Procedure	Rating	Comments	RRL*
DXA VFA	9	Point of service, generally limited to T7-L4. Semi-quantitative and morphology. Learning curve.	Min
X-ray thoracic and lumbar spine	8	High radiation dose, high cost.	Low
Height by stadiometer	4	Indicated height loss that may be related to vertebral fractures.	None
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- Identification of incident or prevalent vertebral fracture indicates increased risk for additional vertebral or other fragility fractures in the following year and should influence therapy.

- VFAs reduced radiation, lower cost, and point of service, make it preferable over spine radiographs as an initial evaluation unless it is contraindicated.

Summary of Literature Review

Noninvasive measurement of bone mineral density (BMD) is a technology that benefits both the patient (as are mammography, blood pressure testing, and cholesterol measurement) and society through its potential to decrease the morbidity, mortality, and cost of fractures associated with osteoporosis through early detection and treatment.

Bone densitometry is the only technology available for accurately measuring of bone mass or predicting fracture risk. Bone measurements have been shown to predict fracture risk as well as or better than cholesterol measurements predict the risk of heart disease or blood pressure measurements predict the risk of stroke. This unique ability of bone densitometry to predict fracture risk makes it an important tool for disease prevention. Before its advent, the diagnosis of osteoporosis depended on the presence of a fragility fracture. With the ability to measure bone mass and the recognition of the relation between reductions in bone mass and increases in fracture risk, the diagnosis of osteoporosis, using World Health Organization (WHO) criteria modified by International Society for Clinical Densitometry (ISCD) to apply to males and females of all races over 50 years of age, can and should be made according to the level of bone mass as determined by BMD before fractures occur. Osteoporosis cannot be diagnosed by BMD in individuals less than 50 years of age using the modified WHO criteria. The only statement that can be made is that if the Z-score (the age-matched database recommended by ISCD for evaluating patients younger than age 50, including pediatric patients) is more than 2 standard deviations below the mean, the BMD is below the expected range for age. Osteoporosis is a clinical diagnosis in patients under age 50. Appropriate etiologies should be investigated (secondary causes for low BMD are numerous), appropriate interventions applied, and appropriate longitudinal monitoring initiated.

Complete assessment of fracture risk and an estimation of benefit from interventions designed to reduce fracture risk should be based on a patient's current relative fracture risk, as determined by measured BMD. Relative fracture risk has been determined using T-score and Z-score. When reporting relative fracture risk, the reference group used must be identified. Ten year fracture probability is the most current proposal for reporting fracture risk and in part depends upon clinical risk factors and BMD. Assessment of appropriate treatment can be made using fracture risk as long as the parameters of the fracture risk are defined.

In specific clinical circumstances, BMD can provide otherwise unobtainable information that is necessary to the clinical decision-making process. In 1989, a subcommittee of the Scientific Advisory Board of the National Osteoporosis Foundation (NOF) described four clinical situations in which knowledge of the patient's bone mass or fracture risk could affect clinical management decisions. These risks included estrogen deficiency, vertebral abnormalities or suspected osteopenia on plain radiography, asymptomatic primary hyperparathyroidism, and long-term corticosteroid therapy if dosage adjustments could be made or other treatment could be initiated to prevent bone loss. Numerous other potential

causative factors for low bone mass can be found in the NOF Physicians Guide to Osteoporosis.

Since the NOF originally published its recommendations, clinical experience in establishing the precision of newer BMD measurement techniques has grown so that serial measurements to determine the efficacy of treatments for osteoporosis are also feasible. Also, knowledge of a patient's bone mass may affect clinical management after organ transplantation.

Estrogen-deficient women constitute one of the largest patient populations potentially affected by these recommendations. Women are more likely to initiate preventive measures for osteoporosis if they are aware of the presence of low bone mass. BMD measurement may help an individual decide whether to begin therapy with selective estrogen receptor modulators (SERMS), or in the appropriate setting of postmenopausal symptoms, with hormone replacement therapy. Other therapies may be offered depending upon the density and clinical factors. In general, a single bone density test can be an extremely powerful tool for patient education and compliance with lifestyle modification and drug therapy. Hence, bone density testing is currently recommended to determine whether pharmacologic intervention is indicated and to establish individual compliance and response in treated patients. The testing, if done in the immediate postmenopausal period, should be performed every 2 years until the possibility of rapid bone loss has been determined or BMD stabilizes on treatment, or, if necessary, to demonstrate continued bone loss (if it occurs) so a patient can determine whether or not to begin therapy.

Guidelines for the Clinical Utilization of BMD Measurement in the Adult Population

An international panel of authorities on BMD headed by Paul D. Miller, MD, Sydney Bonnick, MD, and Clifford Rosen, MD, of the ISCD (see Appendix I for panel members) reached a consensus on the important issues that face physicians who will be ordering, performing, or interpreting BMD measurement for the diagnosis of low bone mass in the adult population. These authors developed guidelines to help physicians use BMD measurement in clinical decision-making. Official positions of the ISCD for BMD practice can be found on the ISCD.org website. The most recent position statements were developed in 2005. Many aspects of BMD measurement and reporting are covered.

The WHO guidelines formed the basis for defining osteoporosis based on levels of low bone mass in patients who have not yet suffered fracture based on dual energy x-ray absorptiometry (DXA) of the spine and femoral neck, and single photon absorptiometry (SPA) of the forearm. These guidelines on BMD measurement are best defined for Caucasian postmenopausal women in whom the risk of osteoporosis is greatest. In addition, the ISCD provided practical guidelines for clinicians to use in assessing which patients should be tested, what changes in bone mass are relevant to define response, what skeletal site(s) should be measured, what techniques should be used, and how clinical reports can enhance the value of BMD. These diagnostic and utilization guidelines will be followed soon by treatment and intervention guidelines. This complete compendium of information will form the basis of clinical decision-making in caring for patients with low bone mass.

Individual scanner protocols for sites to be scanned are encouraged. The protocols should be agreed upon with referring physicians and/or hospitals so that a predictable study outcome will occur. In general, two sites are measured, spine and a hip. If one of these sites cannot be measured, the protocol should outline the next site to be used. Having a protocol should not preclude specific requests by referring physicians who know the patient clinically and manage the care. For instance, a forearm may be ordered in a patient with hyperparathyroidism. If an order is not consistent with protocol without a reasonable clinical indication, an action plan should be developed in the protocol to ensure the scan is warranted clinically. Communication with the referring physician should be part of the protocol.

Scans of the anteroposterior (AP) spine and hip are generally performed. In the event of vertebral fracture, 2 or 3 vertebral fractures can be used to assess BMD. If degenerative change or multiple fractures exclude use of AP spine scan, then both hips can be scanned. If only one hip is available, then a hip and forearm scan can be used. The forearm is best for evaluating hyperparathyroidism. In general, the bone loss in senile or hormonal related osteoporosis is less and slower in the forearm unless the loss is rapid or aggressive and the response to therapy is slower.

BMD predicts a patient's future risk of fracture**.** The ability of bone mass to predict future fracture risk is as valuable as cholesterol testing or blood pressure measurements are for predicting heart attack or stroke and they should be used more widely to identify at-risk patients. Osteoporosis can be diagnosed on the basis of BMD even in the absence of prevalent fractures. Diagnosing osteoporosis before a fracture occurs is important concept advancement. It is justified by the recognized inverse and exponential relationship between low bone mass and future fracture risk and the exceedingly high risk observed for a second fracture once the first fracture has occurred.

The identification of individuals with high risk of fracture is performed on many types of scanners. The diagnosis of osteoporosis can only be made using WHO criteria with DXA scans. Quantitative computed tomography (QCT) can identify patients with low BMD compared to the QCT reference database and can identify patients at risk for fracture. QCT cannot be used to diagnose osteoporosis based on the quantitative BMD value obtained, since it has never been validated for WHO criteria. It is, however, the only other technology besides DXA that is approved for following treatment.

If a patient is originally scanned on DXA but cannot be followed on that scanner and QCT is available, it can be used with the understanding that the first scan becomes the new baseline for the QCT and follow-up is based on this baseline.

BMD measurement provides information that can affect the management of patients. It should be performed in any patient of any age or sex when the result will influence clinical decisions. The clinical decisions that may follow the results are diverse but include whether to initiate hormonal replacement therapy, to diagnose osteoporosis in a young fracturing amenorrheic athlete, or to monitor longitudinal changes in a patient receiving pharmacological therapy to prevent or treat osteoporosis. There are, therefore, a wide variety of clinical decisions that can be made more objectively with knowledge of BMD measurement results.

Choice of the appropriate site(s) for assessing bone mass or fracture risk may vary, depending on the specific circumstances of the patient. Because bone mass is discordant in the younger, perimenopausal population, if the first skeletal site measured is normal, it may be necessary to measure a second skeletal site to make an accurate diagnosis. Measuring more than one skeletal site may also be necessary if artifacts invalidate a particular site. Decisions about which site to measure and how many sites to measure should be the clinician's choice. In general, because cancellous bone changes more rapidly than cortical bone over time or with therapeutic intervention, cancellous bone sites (axial skeleton) may be the preferred sites to measure, though cortical bone sites (mid radius, femoral neck) may also prove valuable and independent data. Also, when performing serial measurements in patients to monitor the natural course of bone loss (or gain) or the response to pharmacological intervention, clinicians must know if the changes are real or within the precision error of a particular measurement and a particular technique. Total body calcium measurement by DXA has the best precision of any site measured by this technology. It is not reimbursed and best performs in the pediatric population. Generally trabecular bone densitometry (TBD) is used for research. No good standard calibration phantom exists for TBD. This is a workable alternative if the proximal femur, spine, or both cannot be evaluated owing to degenerative disease, orthopedic hardware, or both, providing the best estimate of global fracture risk. Body composition data can also be derived from these scans.

Choice of the appropriate technique for BMD measurement in any given clinical circumstance should be based on an understanding of the strengths and limitations of the different techniques. All BMD techniques are good for identifying patients at risk for fracture. The choice of which treatment(s) to use for any patient should also be at the discretion of the physician. In most countries, DXA is the most widely used technique because of its low precision error, low radiation exposure, large clinical experience, and capacity to measure multiple skeletal sites. However, other techniques such as QCT, ultrasound, single x-ray absorptiometry (SXA) of the wrist or calcaneus, peripheral quantitative computed tomography (pQCT), or hand radiogrametry are valuable and may offer information not assessed by DXA. Some of these lower-cost techniques may be used to identify a larger percentage of the population at risk for fracture and low bone mass. Whatever technique is used, quality control and quality assurance are paramount for providing competent patient assessment, including appropriate physician and technologist training. In situations where DXA is not readily accessible to the target population, such as in small rural practices, QCT is the best alternative test, because body CT scanners are widely available. Although QCT (unlike DXA) can selectively evaluate high-turnover cancellous bone and is the best predictor of vertebral fracture risk, its relative disadvantages include higher radiation dose, lower precision, accuracy, and speed, and lower patient throughput because it is not performed on dedicated densitometric equipment. It should be noted that DXA scanners can be successfully mobilized to facilitate patient access.

BMD technologies are not interchangeable. A patient cannot be scanned on DXA and then followed by QCT without establishing a baseline on QCT. The ISCD recommendation is to scan the patient on the same scanner as the original baseline for all follow-up scans.

Quantitative Computed Tomography

QCT was developed in the late 1970s by comparing bone to a series of standard liquids in a phantom for which bone density equivalence had been established. Most systems today use liquid or solid phantoms, although there is a phantomless system using muscle and fat in the patient as a comparative standard. In comparison to DXA, QCT provides a true volumetric measurement of bone milligrams per cubic centimeter (mg/cm^3). It measures trabecular bone density separately from cortical bone. In a two-dimensional QCT scan, the calibration phantom is placed under the patient's back while the body is scanned. A computed radiographic localizer view is obtained to determine the levels of L1 to L3, and each vertebral body is imaged with 1.0-cm section thickness. BMD is then calculated by comparing the spine scan results to the calibrated standards. While this technique is accurate, the reproducibility (precision) can be diminished by variability of slice sampling. The advent of spiral CT scanners and 3-D software that acquire true volumetric images has improved reproducibility. There is also software for measuring the hip that can evaluate cortical, trabecular, and total bone density. The addition of hip measurement by CT greatly expands the diagnostic utility of QCT. The diagnostic utility of QCT is to identify trabecular loss early, but the WHO criteria cannot be applied, and osteoporosis cannot be diagnosed on the BMD value alone. Patients can be identified as having low BMD and followed for treatment or bone loss.

Trabecular bone is metabolically more active than cortical bone, and is the most sensitive indicator of early bone loss and vertebral fracture risk. There is a strong association between vertebral fracture and spinal trabecular BMD as measured by QCT. QCT has been shown to have the strongest ability to discriminate between healthy postmenopausal women and those with vertebral fractures. Spinal trabecular BMD also correlates with trochanteric fracture risk. QCT may be useful in patients with severe scoliosis, facet disease, or hypertropic arthropathy, in whom DXA scans of the spine will yield spuriously elevated density. It may also be more accurate for obese or exceedingly small individuals for whom the assumptions made in DXA calculations regarding soft tissue may be inaccurate.

Areal measurement of BMD versus true volumetric measurement may also affect the accuracy of areal BMD calculations due to their dependence on body size. Increased bone marrow fat content in the very elderly may exaggerate diminished bone density on QCT, as a single energy measurement (SEQCT). This uncertainty related to fat is far lower than the expected biological variation in the normal population. Also the normal database of SEQCT accounts for most variability of marrow fat with age. Radiation dosage from QCT, although higher than the dosage from pencil-beam DXA, is still quite modest when the scan is performed correctly.

Peripheral BMD Measurements

Peripheral BMD measurements, including radiographic absorptiometry (RA) and peripheral DXA and QCT (pDXA and pQCT), are becoming more readily available as techniques to identify people at risk from fracture and low bone mass. Peripheral quantitative ultrasound (QUS), in particular, has been adopted in primary care due to its low cost, portability, ease of use, and lack of ionizing radiation. An international consensus group has reviewed the technology, and

standards have been established to define patients at risk based on standard or modified T scores obtained with this technology.

Peripheral QUS can assess fracture risk in a manner similar to other peripheral BMD measures. Its capacity for assessing rates of change or for monitoring response to therapy has not yet been established. Because it does not measure BMD but rather speed of sound, which may be a parameter of a different quality of bone strength, it may yield additional information regarding fracture risk. However, without specific guidelines to determine whether central testing is necessary, some patients with low bone mass may be missed because their peripheral scans are "normal". QUS should be used only in screening appropriate patients–postmenopausal and elderly who have not had a DXA and are unable to reach a DXA scanner easily because of rural location. This technology is used most frequently in health fairs or other screening events, and if a patient is identified as having an increased risk of fracture he or she should be referred for DXA to confirm the risk of fracture and provide a diagnosis. The DXA then establishes a baseline and follow-up can be performed. QUS can have false negatives and positives depending on the technology and its age. If a patient has multiple risk factors for fracture or low BMD he or she should be referred for DXA evaluation even if QUS is within normal limits. The use of QUS should be extremely limited with the number of DXA scanners available.

Peripheral QCT measures cortical and/or trabecular bone in the ultradistal radius and tibia. It may provide information regarding bone strength and may be particularly beneficial in the pediatric population because it measures BMD independently of bone size and with low radiation exposure. Patients at high risk with intermediate levels of peripheral BMD should probably have axial measurements in addition. However, more research is necessary to define the optimal algorithms for selecting peripheral versus central BMD measures as well as for selecting appropriate diagnostic and treatment thresholds for all types of densitometry methods and for all manner of patients.

BMD testing should be accompanied by a clinical interpretation. The computer printout data provided by BMD equipment manufacturers do not fully provide the type of clinical information that the primary care physician needs in order to direct patient care. BMD results have wide implications for clinical decisions in the care of patients with low bone mass and may lead to broader diagnostic and therapeutic interventions than can be provided by blood pressure measurements or blood chemistry results. A brief narrative report that correlates the bone-mass measurement to a technician-obtained patient questionnaire database can allow the clinician interpreting the BMD results to suggest wider diagnostic and intervention possibilities to the primary care physician. In pediatric patients with risk factors for low bone mass, it is mandatory that DXA scans be performed using specialized pediatric software provided by the equipment manufacturer.

BMD in Men

Recent recognition of osteoporosis as a significant health problem in men, usually related to secondary causes and worsening with age, has raised awareness for the need to assess this population for BMD in the appropriate setting. Prior to age 50, only the Z-score should be used. After age 50, the T-score is used with WHO criteria for diagnosis. Reference databases should be male.

BMD in Premenopausal Women and Children

Specific reasons for evaluating premenopausal women and children should exist before performing the density measurement. Potential for misdiagnosis exists. Steroid treatment, eating disorders, amenorrhea and genetic disorders are among the reasons to evaluate this group. Reporting of pediatric BMD is controversial. Debate as to the utility of DXA and QCT is ongoing. Appropriate age-matched and pediatric databases are required, but have limited data at this time.

Vertebral Fracture Assessment

Vertebral fracture assessment (VFA) is a relatively new application for DXA scanners that allows evaluation for occult fractures of the spine at the time the patient is being evaluated for BMD. The term VFA is used to identify the assessment for billing, approved by Medicare, since manufacturers have used several other proprietary names for the same technique. Vertebral fractures are the most common osteoporotic fracture. Traditionally x-rays of the thoracic and lumbar spine are used to identify compression fracture if fracture is suspected. The radiation dose and cost of x-rays are significantly higher than those of VFA. The problem is that up to 70% of osteoporotic compression fractures are asymptomatic. The importance of identifying these fractures is that they are predictors for future fracture, that increase with the severity and number of fractures identified. The identification of fracture also changes the acuity of treatment for osteoporosis. Many patients with fractures have an osteopenic BMD, but the presence of a fracture then changes the diagnosis to osteoporosis. Prevention of further fracture is cost effective.

Less severe grade 1 fractures may be difficult to identify, and if there is only one present, there is much less risk of subsequent fracture. Grades 2 and 3 fractures are readily identified. The technique is usually limited to T7-L4, however the overwhelming majority of the osteoporotic fractures occur at these levels.

Criteria for use of VFA include: documented height loss of greater than 2 cm or reported height loss of 4 cm since age 21; history of a fracture after age 50; treatment with long term steroids; undocumented history of back pain suspicious for vertebral fracture. (For ISCD position statements see www.iscd.org.)

The evaluation for VFA uses the Genant semiquantitative analysis technique with morphometry, semi-automated, as an adjunct in difficult cases.

Summary of Key Recommendations

BMD measurement is used to identify patients with low bone density and increased fracture risk. DXA is the gold standard and the only BMD technology for which WHO criteria for diagnosis of osteoporosis, originally for postmenopausal Caucasian women over age 65, can be used. ISCD has expanded the diagnostic category to include patients over age 50 of any race or gender (ISCD position statement). The sites that are used for diagnosis are the AP spine, femoral neck (ISCD includes total hip, and forearm [distal one-third radius]). Follow-up for treatment can be performed using DXA and QCT only. All other measurements are peripheral and for identifying individuals at risk for fracture and low BMD (pDXA, pQCT, SXA, QUS). Hyperparathyroidism is an exception to routine BMD testing

where the forearm is essential for diagnosis. Another exception is pediatric patients where DXA can measure spine, but total body calcium is preferred because it helps reduce the issue of following patients with growing bones.

T-scores are used for men and women after age 50 or menopause to make a diagnosis and assess fracture risk. Z-scores are used for all individuals under age 50 to determine low bone density. Fracture risk is not assessed based on BMD in individuals under age 50. No agreed upon fracture risk assessment exists. Multiple ways of expressing fracture risk do exist and each needs to be used defining the reference data. WHO and NOF will, in the near future, provide a 10-year absolute fracture risk model that will be available for DXA software. Other modalities have variable fracture risk based on the study in which the relative risk of fracture was developed. Vertebral fracture assessment can be performed with DXA at the point of service at a lower cost and with less radiation than x-rays. Identification of a prevalent vertebral fracture has an independent risk for future fracture in the following year. Each additional fracture significantly raises the risk of another osteoporotic fracture.

Abbreviations

- BMD, bone mineral density
- DXA, dual x-ray absorptiometry
- Min, minimal
- QCT, quantitative computed tomography
- PA, posterior-anterior
- pQCT, peripheral quantitative computed tomography
- SXA, single x-ray absorptiometry
- QUS, quantitative ultrasound
- VFA, vertebral fracture assessment
- WHO, World Health Organization

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate selection of bone mineral density (BMD) measurement procedures to evaluate patients at risk for osteoporosis or to diagnose osteoporosis

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Richmond BJ, Dalinka MK, Daffner RH, Bennett DL, JA Jacobson, Resnik CS, Roberts CC, Rubin DA, Schweitzer ME, Seeger LL, Taljanovik M, Weissman BN, Haralson RH, Expert Panel on Musculoskeletal Imaging. Osteoporosis and bone mineral density. [online publication]. Reston (VA): American College of Radiology (ACR); 2007. 12 p. [62 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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1998 (revised 2007)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

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GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Musculoskeletal Imaging

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: American College of Radiology (ACR), Expert Panel on Musculoskeletal Imaging. Osteoporosis and bone mineral density. Reston (VA):

American College of Radiology (ACR); 2001. 17 p. (ACR appropriateness criteria). [49 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria®. Relative radiation level information. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 6, 2001. The information was verified by the guideline developer as of June 29, 2001. This summary was updated by ECRI on July 31, 2002. The updated information was verified by the guideline developer on October 1, 2002. This NGC summary was updated by ECRI Institute on November 13, 2007.

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